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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/387,340	08/31/1999	PHILIP NEEDLEMAN	MON-102.0-CO	2465

22907 7590 08/20/2003

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EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	**PAPER NUMBER**
1642	33

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/387,340	Applicant(s) NEEDLEMAN ET AL.	
	Examiner MINH-TAM DAVIS	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 07/07/03 01/25/02 & 07/31/01
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The submission of the amendments after final of paper No:11, on 07/31/01, paper No: 14 of 09/07/01 and the amendments after the CPA filing of paper No: 17 of 02/01/02, paper No: 19 of 02/21/02, the amendment and the Declaration of paper No:22 of 04/18/02, the amendment of paper No:24 of 05/21/02, and the amendment of paper No: 25 of 07/11/02 is acknowledged and has been entered.

In paper No: 17 of 02/01/02, Applicant cancels claims 11, 12, 14-15, and adds new claims 44-47, which are related to claims 11, 12, 14-15. Claims 44-47 has been renumbered as claims 33-36, according to rule 126.

In paper No: 19 of 02/21/02, Applicant adds new claims 48-51, which are related to claims 33-36. Claims 48-51 has been renumbered as claims 37-40, according to rule 126.

The restriction requirement of paper No:23 on 05/21/02 has been withdrawn, and all the species are rejoined.

Accordingly, claims 33-40 are being examined.

It is noted that the 112, first paragraph, enablement of the final rejection of paper No: 7, on 02/14/01, of previous claims 11-12, 14, 15, which are related to the pending claims 33-40 has been withdrawn, in view of US 6,410,022 B1, which is issued on 06/25/02, after the date of the final rejection of paper No: 7, on 02/14/01, and said enablement rejection is replaced with the following rejections.

It is further noted that the arguments in the above submitted amendments addressing the 112, first paragraph, enablement issue are moot in view of the present withdrawn of the 112, first paragraph, enablement.

It is also noted that although the claimed invention and US 6,410022 B1 have the same assignee, no double patenting or obviousness-type double patenting is made between the claimed invention and US 6,410022 B1, because the assignee was not common at the time the invention was made (see attached interview for recent common assignee).

The following are the remaining rejections.

PRIORITY DATE

The priority date of the instant application has been determined to be 05/30/95 in view of the Declaration, in which it was disclosed on page 064 that pre-bleeds on 05/30/95 was done in experiments using CETP peptide with MAP (multiple antigenic peptide) antigen carrier1`.

SUPPLEMENTAL INFORMATION DISCLOSURE

The submission of supplemental information disclosure of 07/31/01 and 01/25/02 is acknowledged. Two signed PTO-1449 forms are enclosed herewith.

A request for consideration of US 6,410,022, US 6,555,113 and US 6,284533 on 07/07/03 is acknowledged. A submission of a supplemental information disclosure of 05/07/03, as recited in the request of 07/07/03 however is missing in the instant file.

The above US 6,410,022, US 6,555,113 and US 6,284533 have been considered, and a signed form is enclosed herewith.

OBVIOUSNESS TYPE DOUBLE PATENTING

In the response of paper No: 11, Applicant recites that a provisional terminal disclaimer is filed herewith. However the terminal disclaimer is missing in the file.

This rejection however is withdrawn, in view that all the present claims 33-40 are drawn to a process for producing antibodies to cholesteryl ester transfer protein (CETP) in the blood of a human, comprising administering a CETP immunogen protein, whereas all the claims 1-11, 15-16, 22-27 of copending application SN=08/934367 are drawn to a process for producing antibodies to cholesteryl ester transfer protein (CETP) in the blood of a human, comprising administering a CETP immunogen DNA molecule, which is a separate and distinct invention.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER, NEW REJECTION

Claims 33, 35, 37, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 33, 35, 37, 39 are drawn to a process for producing antibodies to cholesteryl ester transfer protein (CETP) in the blood of a human, whose blood contains CETP, comprising

(a) administering an inoculum to said human, said inoculum comprising a vehicle containing a CETP immunogen, wherein said CETP immunogen has (i) an exogenous antigenic carrier polypeptide, that is peptide-bonded to (ii) an immunogenic polypeptide of "about 10 to no more than thirty" amino acid residues of human CETP amino acid sequence (SEQ ID NO:28) and comprising amino acids 465 through 475 of human CETP amino acid sequence;

(b) repeating said administration, sufficient for said CETP immunogen to cause, by an autogeneic immunological response, production of antibodies which binds to CETP in the blood of said human, and

(c) maintaining said antibodies which bind to CETP in the blood of said human by further administration of said inoculum,

whereby the binding of said antibodies to CETP in said blood lessens the transfer of cholesteryl ester from HDL and increases the concentration of HDL cholesterol in the blood of said human (claim 33).

Said exogenous antigenic carrier polypeptide is selected from the group consisting of tetanus toxoid, tuberculin purified protein derivative, diptheria toxoid, thyroglobulin, and a branched oligolysine (claim 35).

Said inoculum also comprises an adjuvant selected from the group consisting of incomplete Freud's adjuvant (IFA) and alum (claims 37, 39).

Applicant asserts in paper No:25 that the limitation of "about 10 to no more than thirty amino acid residues of human CETP" is supported in the specification in the paragraph bridging pages 15 and 16.

Contrary to Applicant's assertion, the limitation of "about 10 to no more than thirty amino acid residues of human CETP" is not supported in the specification. The specification in the paragraph bridging pages 15 and 16 only discloses that it is preferred to use a polypeptide having a length of about 10 to "about" 30 amino acid residues, and more preferably, a length of about 20 to 30 residues.

REJECTION UNDER 35 USC 102 (e), NEW REJECTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 34, 36, 38, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,410022 B1.

The applied reference seems to have a common assignee with the instant application (see interview summary of 07/06/03). Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 34, 36, 38, 40 are drawn to a process for producing antibodies to cholesteryl ester transfer protein (CETP) in the blood of a human, whose blood contains CETP, comprising

(a) administering an inoculum to said human, said inoculum comprising a vehicle containing a CETP immunogen, wherein said CETP immunogen has (i) an exogenous antigenic carrier polypeptide, that is peptide-bonded to (ii) an immunogenic polypeptide consisting of amino acids 461 through 476 of human CETP amino acid sequence;

(b) repeating said administration, sufficient for said CETP immunogen to cause, by an autogeneic immunological response, production of antibodies which binds to CETP in the blood of said human, and

(c) maintaining said antibodies which bind to CETP in the blood of said human by further administration of said inoculum,

whereby the binding of said antibodies to CETP in said blood lessens the transfer of cholesteryl ester from HDL and increases the concentration of HDL cholesterol in the blood of said human (claim 34).

Said exogenous antigenic carrier polypeptide is selected from the group consisting of tetanus toxoid, tuberculin purified protein derivative, diptheria toxoid, and thyroglobulin (claim 36).

Said inoculum also comprises an adjuvant selected from the group consisting of incomplete Freud's adjuvant (IFA) and alum (claims 38, 40).

US 6,410022 B1 teaches a method for decreasing the level of cholesteryl ester transfer protein activity in a human or other animal, or a method for increasing the level of circulating high density lipoprotein in a human or other animal, comprising administering to the human or animal an antigenic vaccine hybrid peptide comprising a helper T cell epitope portion linked to a B cell epitope portion, comprising six to 26 consecutive amino acids in the carboxyl terminal 26 amino acids of human cholesteryl ester transfer protein. (claims 14-16)

US 6,410022 B1 further teaches an anti-CETP vaccine peptide comprising a helper T cell epitope and a B cell epitope portion comprising a carboxyl terminal region of human CETP. In addition, US 6,410022 B1 teaches that a 31 amino acid anti-CETP vaccine peptide is designed having the amino acids of SEQ ID NO:2, in which amino acids 2-15 of SEQ ID NO:2 is a fragment of tetanus toxoid protein, and amino acids 16-

31 of SEQ ID NO:2 is the same as amino acids 461 to 476 containing the neutral lipid transfer domain of human CETP and known to be recognized by ant-human CETP-Mab TP2 (Example 1 on column 14).

Moreover, US 6,410022 B1 teaches that the CETP vaccine peptide may be administered by any route for vaccination (column 12, last paragraph), and that a common and traditional approach for vaccinating human is to administer an initial dose of a vaccine, and then follow up by one or more booster doses of the vaccine (column 13, lines 34-40).

US 6,410022 B1 teaches that the helper T cell epitope could be tetanus toxoid, diptheria toxoid, tuberculin purified protein derivative (column 6, last paragraph, bridging column 7). US 6,410022 B1 teaches that pharmaceutically acceptable adjuvants, such as alum may be mixed with the vaccine peptide, and that other adjuvants such as incomplete Freud's adjuvant are well known (column 10, last paragraph, bridging column 11).

Although US 6,410022 B1 does not teach that tetanus toxoid is peptide bonded to amino acids 461 to 476 in SEQ ID NO:2, it is an inherent property of the vaccine peptide of SEQ ID NO:2 taught by US 6,410022 B1, because it is well known in the art that individual amino acids of a peptide are linked together by peptide bonding.

Thus the CETP immunogen and adjuvant in the claimed method seems to be the same as the vaccine peptide and adjuvant taught by US 6,410022 B1

Because the method of the prior art comprises the same method steps as claimed in the instant invention using the same composition, the claimed method is

anticipated because the method will inherently lead to the claimed effects. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

REJECTION UNDER 35 USC 103, NEW REJECTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-40 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,410022 B1, in view of US 4,957737 and Butz S et al, 1994, Peptide Res, 7(1): 20-3.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29,

1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 34- 40 are drawn to a process for producing antibodies to cholesteryl ester transfer protein (CETP) in the blood of a human, whose blood contains CETP, comprising

(a) administering an inoculum to said human, said inoculum comprising a vehicle containing a CETP immunogen, wherein said CETP immunogen has (i) an exogenous antigenic carrier polypeptide, that is peptide-bonded to (ii) an immunogenic polypeptide of about 10 to no more than thirty amino acid residues of human CETP amino acid sequence (SEQ ID NO:28) and comprising amino acids 465 through 475 of human CETP amino acid sequence or (ii) an immunogenic polypeptide consisting of amino acids 461 through 476 of human CETP amino acid sequence;

(b) repeating said administration, sufficient for said CETP immunogen to cause, by an autogeneic immunological response, production of antibodies which binds to CETP in the blood of said human, and

(c) maintaining said antibodies which bind to CETP in the blood of said human by further administration of said inoculum,

whereby the binding of said antibodies to CETP in said blood lessens the transfer of cholesteryl ester from HDL and increases the concentration of HDL cholesterol in the blood of said human (claims 33- 34).

Said exogenous antigenic carrier polypeptide is selected from the group consisting of tetanus toxoid, tuberculin purified protein derivative, diptheria toxoid, thyroglobulin, and branched oligolysine (claims 35-36).

Said inoculum also comprises an adjuvant selected from the group consisting of incomplete Freud's adjuvant (IFA) and alum (claims 37-40).

US 6,410022 B1 teaches a method for decreasing the level of cholesteryl ester transfer protein activity in a human or other animal, or a method for increasing the level of circulating high density lipoprotein in a human or other animal, comprising administering to the human or animal an antigenic vaccine hybrid peptide comprising a helper T cell epitope portion linked to a B cell epitope portion, comprising six to 26 consecutive amino acids in the carboxyl terminal 26 amino acids of human cholesteryl ester transfer protein.

US 6,410022 B1 teaches an anti-CETP vaccine peptide comprising a helper T cell epitope and a B cell epitope portion comprising a carboxyl terminal region of human CETP. In addition, US 6,410022 B1 teaches that a 31 amino acid anti-CETP vaccine peptide is designed having the amino acids of SEQ ID NO:2, in which amino acids 2-15 of SEQ ID NO:2 is a fragment of tetanus toxoid protein, and amino acids 16-31 of SEQ ID NO:2 is the same as amino acids 461 to 476 containing the neutral lipid transfer domain of human CETP and known to be recognized by anti-human CETP-Mab TP2 (Example 1 on column 14).

Further, US 6,410022 B1 teaches that the more preferably, the B cell epitope (or CETP-related) portion of the vaccine peptides is any fragment of the carboxyl terminal

region of CETP which is at least eleven consecutive amino acids in length, which retains the conformation of the carboxyl terminal 26 amino acid region of CETP, and which is involved in the neutral lipid binding and/or transfer activity of CETP (column 7, lines 19-27).

Moreover, US 6,410022 B1 teaches that the CETP vaccine peptide may be administered by any route for vaccination (column 12, last paragraph), and that a common and traditional approach for vaccinating human is to administer an initial dose of a vaccine, and then follow up by one or more booster doses of the vaccine (column 13, lines 34-40).

US 6,410022 B1 teaches that the helper T cell epitope could be tetanus toxoid, diptheria toxoid, tuberculin purified protein derivative, which have been used as immunogenic carrier for human vaccination, for activating helper T cells which in turn stimulate B cell growth and differentiation (column 6, last paragraph, bridging column 7).

US 6,410022 B1 teaches that pharmaceutically acceptable adjuvants, such as alum may be mixed with the vaccine peptide, and that other adjuvants such as incomplete Freud's adjuvant are well known (column 10, last paragraph, bridging column 11)

In addition, US 6,410022 B1 teaches that in rabbits injected with the above 31 amino acid anti-CETP vaccine peptide, antibody specific for recombinant human CETP was produced (Example3), and two rabbits that have the highest anti-CETP antibody titers, show a 2-5 fold increase in HDL-C concentrations as compared to prebleed

plasma samples and control rabbits and rabbits with lowest titer of anti-CETP antibody (Example 4). US 6,410022 B1 teaches that in transgenic mice that express human CETP, administration of said 31 amino acid anti-CETP vaccine peptide produces antibody specific for recombinant human CETP, competing with the antibody TP2 for binding to CETP (Example 5). US 6,410022 B1 teaches that it is known in the art that the monoclonal antibody TP2, the epitope of which is localized in the carboxyl terminal 26 amino acids of human CETP , i.e. amino acids 451-476 of human CETP, inhibits completely the cholesteryl ester and TG transfer activity (column 2, paragraph before last). US 6,410022 B1 teaches that a number of in vivo studies using animal models or human have indicated that CETP activity can affect the level of HDL-C, wherein an increase in CETP activity can produce a decrease in HDL-C levels relative to LDL and/or VLDL-C levels, which in turn is correlated with an increased susceptibility to atherosclerosis (column 2, last paragraph bridging column 3).

US 6,410022 B1 does not teach an CETP immunogen that has (i) an exogenous antigenic carrier polypeptide, that is peptide-bonded to (ii) an immunogenic polypeptide of about 10 to no more than thirty amino acid residues of human CETP amino acid sequence (SEQ ID NO:28) and comprising amino acids 465 through 475 of human CETP amino acid sequence. US 6,410022 B1 does not teach that the exogenous antigenic carrier polypeptide is thyroglobulin or branched oligolysine

US 4,957737 teaches the use of an immunogenic carrier thyroglobulin in an AIDs vaccine (claim 4). .

Butz S et al teach that small peptides cannot initiate an immune response unless they are bound to suitable carrier molecules and that a resin-immobilized branched oligolysine has been used with synthetic peptides to raise antibodies against the peptides (p. 20, first column, and first paragraph of second column).

It would have been *prima facia* obvious to a person of ordinary skill in the art at the time the invention was made to use the method taught by US 6,410022 B1 in a human comprising administering an anti-CETP vaccine peptide for producing an antibody specific to CETP. One of ordinary skill in the art would have expected that similar to rabbits and mice models taught by US 6,410022 B1, a treated human would produce an antibody specific to the carboxyl terminal of CETP, and an increase in the level of HDL cholesterol, because the antibody produced would have similar property as the known antibody TP2 with overlapping epitope, and would lessen the activity of CETP, which is known for affecting the level of circulating cholesterol-containing HDL, as taught by US 6,410022 B1. It would have been obvious to replace the CETP peptide portion of an anti-CETP vaccine peptide taught by US 6,410022 B1 with an immunogenic polypeptide of about 10 to no more than thirty amino acid residues of human CETP amino acid sequence (SEQ ID NO:28) and comprising amino acids 465 through 475 of human CETP amino acid sequence, because the amino acids 465 through 475 of human CETP in the claimed method would encompass amino acids 461 to 476 containing the neutral lipid transfer domain of human CETP and known to be recognized by anti-human CETP-Mab TP2 taught by US 6,410022 B1, and thus would produce the same results, i.e. producing antibodies that are specific to CETP and inhibit

CETP activity. It would have been obvious to use an immunogenic carrier in the vaccine, including tetanus toxoid, tuberculin purified protein derivative, diptheria toxoid, all taught by US 6,410022 B1, thyroglobulin taught by US 4,957737, and branched oligolysine taught by Butz et al, because they would produce the same results, i.e. stimulating the immune response.

One of ordinary skill in the art would have been motivated to treat a human with an anti-CETP vaccine peptide with a reasonable expectation of success. The motivation is obvious, i.e. decreasing susceptibility to atherosclerosis in a human, because an increase in CETP activity can produce a decrease in HDL-C levels relative to LDL and/or VLDL-C levels, which in turn is correlated with increased susceptibility to atherosclerosis, as taught by US 6,410022 B1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

July 29, 2003